

REMARKS

It is respectfully requested that the above amendments be entered under the provisions of 37 C.F.R. §1.116(b); that this application be reconsidered in view of the above amendments and the following remarks; and that all of the claims remaining in this application be allowed.

Claim Amendments

Applicants have requested that Claim 25 be amended to reflect that the amount of tantalum in the composition is from 40.2 to 53.4 weight percent. Support for this range is found in the Table on pages 17 and 18 of the specification. Applicants have further requested that Claim 25 be amended to reflect that the amount of ethylene vinyl alcohol copolymer to the tantalum contrast agent is from 0.077 to 0.995. Support for the lower value is found in the Table at page 17, wherein this ratio for 40.2 weight percent tantalum is recited as 0.077. Support for the upper value is readily derived from the upper limit of the ethylene vinyl alcohol recited in Claim 25 (40 weight percent) and the lower limit of the tantalum also recited in that claim (40.2 weight percent).

Claim 26 has been amended to recite that the tantalum contrast agent is employed at a concentration of from 41.7 to 50.4 weight percent. Support for this amendment is found in the Table beginning on page 17.

Claims 26-29 have been amended to correct claim dependency.

Claim 30 has been canceled.

The above amendments comply with formalities raised in a rejection made under 35 U.S.C. §112, second paragraph, which was newly raised in the final Office Action. As such, their entry under the provisions of 37 C.F.R. §1.116(b)(1) is deemed proper. Furthermore, as these amendments will render the application in better form for appeal, their entry under the provisions of 37 C.F.R. §1.116(b)(2) is also deemed proper.

No new matter has been introduced by the above amendments and, accordingly, entry of these amendments is requested.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Rejection Under 35 U.S.C. §112, second paragraph

Claims 25-30 stand rejected under 35 U.S.C. §112, second paragraph, as the phrase “from greater than 40 to 60 weight percent” is allegedly indefinite. While Applicants disagree with this rejection, Applicants have requested amendments to Claims 25 and 26 wherein the objected to terms have been deleted and replaced it with a specific range for the contrast agent. Accordingly, upon entry of these amendments, this rejection will be moot.

Withdrawal of this rejection is requested.

Rejection Under 35 U.S.C. §103(a)

Claims 1, 4-8, 10-16 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Whalen et al., U.S. Patent Publication No. US 2002/0090339 (“Whalen”) in view of Patterson, et al., U.S. Patent Publication No. US 2004/0224864 (“Patterson”); or Porter, et al., U.S. Patent Publication No. US 2004/0197302 (“Porter”). For the following reasons, this rejection is traversed.

Before directly addressing this rejection, Applicants assume that this rejection is intended to be applied to now presented Claims 25-29 as previously Claims 1, 4-8, 10-16, 24 and 30 are canceled.

In addressing this rejection, it appears that there are two issues raised by these references. The first is relevance of the Whalen reference. The Office recites that Applicants' previously argued that Whalen did not recite the inclusion of a thixotropic agent. This is simply wrong.

Applicants' arguments presented in their response to the prior Office Action stated the following:

“...Suffice it to note that Whalen, et al. fail to disclose the use of contrast agent in the amounts recited herein coupled with the ratio of polymer (ethylene vinyl alcohol copolymer) to contrast agent (tantalum) as now required in the claimed invention. Nor does Whalen suggest any benefit that could be achieved by such a combination of contrast agent and polymer.”

Any reference to a thixotropic agent in that response was with reference to the Patterson and Porter references.

The second issue to be addressed is the proper construction of the term “about” in the Whalen reference. The Office seems confused as to whether this term should be applied to the pending claims or to Whalen. For example, with citation to Amgen v. Chugai, 927 F2d. 1200 (Fed. Cir. 1991), the Office is relying upon this case to substantiate that the term “about” is indefinite as it gave no hint as to which value between the prior art value of 128,620 and 160,000 constituted infringement. Indefiniteness is not a substitute for obviousness. Moreover, neither the previously presented claims nor the now pending claims recited the term “about” as it relates to the lower limit that relates to the prior art. In fact, now presented Claim 25 recites that the amount of contrast agent ranges from 40.2 to 53.4 weight percent tantalum.

In order to expedite prosecution, Applicants will assume arguendo that the Office intended to state that the compositions of this invention are distinguished over Whalen by virtue of the amount of contrast agent employed and that Whalen's teaching of “about 40 weight percent contrast agent” renders obvious either the prior claim of greater than 40 weight percent to 60 weight percent or the now claimed range of from 40.2 to 53.4 weight percent tantalum. If

such is the case, the sole issue to be addressed turns on the meaning of the word "about" as it relates to Whalen.

With regard to the term "about", it is axiomatic that the claims are viewed relative to the specification. As to Whalen, this reference discloses high viscosity embolic compositions having "about 40 weight percent" of a contrast agent such as tantalum. Whether this recitation would encompass amounts greater than 40% is dependent on the teachings of the specification relative to the knowledge of the skilled artisan. In this regard, Whalen discloses that "sufficient amounts" of the contrast agent are added to the composition which is "even more preferably about 30 weight percent". Whalen further teaches that, for a water insoluble contrast agent, stirring is employed to effect homogeneity of the composition.

Given that Whalen's composition has high viscosity, preferably employs 30 weight percent contrast agent and requires stirring to effect homogeneity of the composition when the contrast agent is water insoluble (e.g., tantalum), why would the skilled artisan interpret about 40% to read on amounts greater than 40% for water insoluble contrast agents as such would render the mixing process more difficult. Indeed, the mixing problem is sufficiently difficult that Whalen recites that the composition is preferably heated to facilitate formation of a uniform suspension.

Stated another way, if the composition which preferably employs 30% of tantalum requires heating to effect formation of a uniform suspension, why would the skilled artisan construe about 40% to be higher than 40% as such would only exacerbate the problems revealed by Whalen.

It is this invention's discovery that notwithstanding these teachings by Whalen, the use of greater than 40% tantalum is not only feasible but provides for unexpected results when so used.

Finally, in making this rejection, the Office has failed to provide any rationale as to why the skilled artisan would construe the term "about 40%" to read on greater than 40%.

In view of the above, Applicants submit that this rejection is in error. Withdrawal of this rejection is requested.

Obviousness-Type Double Patenting Rejection

Claims 25-30 stand rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-6 of Greff, et al., U.S. Patent No. 5,667,767 (“Greff”) and Claims 1-8 and 16-23 of Evans, et al., U.S. Patent No. 5,695,480 (“Evans”). For the following reasons, these rejections are traversed.

A rejection under the judicially created doctrine of obviousness-type double patenting is analogous to an obviousness rejection under 35 U.S.C. §103(a) except that the patent principally underlying the rejection is not construed as prior art. Therefore, any analysis of such a rejection parallels the analysis of an obviousness rejection. See, e.g., MPEP §804.

As to the ‘767 patent, the cited claims fail to disclose the use of tantalum in excess of 40 weight percent in combination with a ratio of ethylene vinyl alcohol copolymer to tantalum of greater than 0.07 when using such high levels of tantalum. The Office alleges that the term “about” in the cited claims of the ‘767 patent reads on amounts greater than 40 percent tantalum.

With regard to the term “about”, it is axiomatic that the claims are viewed relative to the specification. As to Greff, Applicants acknowledge that this reference discloses embolic compositions having “about 40 weight percent” of a contrast agent such as tantalum. Whether this recitation would encompass amounts greater than 40% is dependent on the teachings of the specification relative to the knowledge of the skilled artisan. In this regard, Greff discloses that “sufficient amounts” of the contrast agent are added to the solvent to achieve an effective concentration of contrast agent and that preferably such amounts are from about 10 to about 40 weight percent and “even more preferably about 35 weight percent”. Greff further teaches that, for a water insoluble contrast agent, stirring is employed to effect homogeneity of the composition.

Given that Greff's compositions preferably employs 35 weight percent contrast agent and requires stirring to effect homogeneity of the composition when the contrast agent is water insoluble (e.g., tantalum), why would the skilled artisan interpret about 40% to read on amounts greater than 40% for water insoluble contrast agents as such would render the mixing process more difficult.

It is this invention's discovery that notwithstanding these teachings by Greff, the use of greater than 40% tantalum is not only feasible but provides for unexpected results when so used.

Finally, in making this rejection, the Office has failed to provide any rationale as to why the skilled artisan would construe the term "about 40%" to read on greater than 40%.

In view of the above, Applicants submit that this rejection is in error. Withdrawal of this rejection is requested.

As to the '480 patent, the cited claims are focused on the use of a water insoluble contrast agent has an average particle size of about 10 microns or less. Claim 3 of that patent recites that the solvent is DMSO. Claim 5 recites that the water insoluble contrast agent is tantalum and Claim 14 recites that the polymer is an ethylene vinyl alcohol copolymer. As with the '767 patent, the cited claims of the '480 patent fail to disclose the use of tantalum in excess of 40 weight percent in combination with a ratio of ethylene vinyl alcohol copolymer to tantalum of greater than 0.07 when using such high levels of tantalum.

In contrast to Greff, Evans teaches that the preferred amount of tantalum is in fact 30 weight percent which is even further removed from that of Greff which is 35 weight percent. Indeed, Example 1 of Evans uses about 20 weight percent tantalum.¹ Accordingly, as Greff does not create a *prima facie* case of obviousness and hence does not present a valid obviousness-type

¹ Assuming a density of 1.10 g/mL for DMSO, the total weight of the composition is 148 g of which 30 g is tantalum ($30/148 \times 100 = 20.3\%$)

double patent rejection, the same is true for Evans which is even further removed than Greff from the claimed invention.

Withdrawal of these rejections is requested.

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-4972. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-4972. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-4972.

Respectfully submitted,

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By



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